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DAILY NEWS**With Bolstered TSCA Program, Few Surprised Over Trump Push To Kill IRIS**

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The Trump administration's proposal to eliminate EPA's Integrated Risk Information System (IRIS) chemical assessment program as part of its fiscal year 2018 budget request is surprising few observers of the influential program, especially given the controversy that has surrounded it and the stepped-up efforts to bolster the agency's Toxic Substances Control Act (TSCA) programs.

But several industry and other sources voiced skepticism that the Trump administration will be able to eliminate the program, given lack of political leadership at the agency.

"What's the realistic prospect this ever gets done?" one industry source asks, pointing to the number of empty political appointee slots at EPA. "Like everything Trump, none of this will happen quickly because nobody is there."

Others also said they expect internal push-back from EPA program offices, as the program's elimination would force them to seek risk and other data for their regulatory decisions from other sources, possibly including stricter values from regulators in California and Europe, and potentially inconsistent use of values across regions and programs.

IRIS has been long criticized by regulated entities for the stringency of its assessments and its opacity.

It has been on the Government Accountability Office (GAO) list of programs at "high risk" of waste, fraud or abuse for its inability to produce assessments in a timely way for several years. Since a critical 2011 National Academy of Sciences review of its draft formaldehyde assessment, the program has produced only a handful of final assessments.

Given the criticisms, and administration efforts to bolster the agency's TSCA programs to implement the new law that the administration's FY18 budget proposes to eliminate IRIS is not surprising, sources say.

"It's not surprising when you think about the GAO work and its fundamental issues over the years, and with this administration and budget cuts," says the first industry source. This source, like others, suggested that building up EPA's toxics office, newly empowered to assess and manage the risks of existing chemicals with the overhaul of TSCA, could better perform work that IRIS was previously tasked with doing.

Another industry source went so far as to suggest that maintaining IRIS while ramping up the toxics program -- one of the few areas where the FY18 budget proposes a nearly \$14 million increase -- would be redundant. Further, this source sees language requiring standards of scientific quality in the statute overhauling TSCA as an important improvement for EPA's risk analysis programs.

While several sources questioned whether the administration would be able to eliminate the program, a third industry source also pointed to language in the agency's budget plan that requires responses from program offices regarding the proposal, and a schedule for crafting the EPA's proposal for the administration's final budget proposal.

"It's the first inning. This is from on high, 'These are the places to create savings,'" this industry source says. "Each program office then makes their response. That document will be very interesting. What do program officers feel like they can preserve, because they have to sacrifice something?"

Internal Push-Back

And a former EPA source indicates there will be internal push-back on the proposal because IRIS assessments are requested by program offices. IRIS managers in late 2015 published the program's agenda for the next several years --

after months of cross-agency discussions about program offices' needs for risk values and how best to prioritize them to make IRIS' to-do list.

"There's going to be huge push-back. Within EPA, IRIS is considered wonderful by people that need it, and states that need it," says one former EPA source. But other offices, like the pesticides and water offices, "go their own ways" and are in varying degrees independent.

Details of the agency's budget plan are contained in a March 21 memo from David Bloom, the agency's acting chief financial officer, which indicates how officials plan to implement the administration's proposal to cut EPA's FY18 funding by more than \$2 billion -- or 31 percent -- compared to FY16 levels.

It also lays out the deadlines for crafting EPA's budget proposal. Proposed FY 2018 performance target revisions from national program managers were due April 7 and OMB-approved FY17 - FY18 performance measures and targets are due by the national program managers and the chief financial officer's staff by April 18. Pre-dissemination review certification is to be completed by EPA's acting assistant administrators by April 25.

Bloom's memo provides a comprehensive look at what the budget request will mean for scores of EPA programs, among them the proposal to completely eliminate the IRIS program and EPA's usage of IRIS dose-response analyses for setting standards and other decisionmaking.

The memo indicates that the administration proposes dropping the research office's human health risk assessment portfolio by \$5.6 million and 105 full time equivalent employees (FTE) in the FY18 budget. "This change reflects the elimination of the IRIS program and the re-focusing on core statutory obligations," the memo states.

A second former EPA source also points out different program offices would be impacted in varying degrees if IRIS were to be eliminated. This source, like the first, noted that the pesticides office has performed its own assessments throughout IRIS' existence and will be little impacted. This source suggests that the toxics office could be affected, because in its short history of operating under the new TSCA, the office has relied on IRIS assessments as the basis for their risk assessments. This is a practice that former Obama administration toxics chief Jim Jones indicated in an interview with *Inside EPA* shortly before leaving office last January would continue.

But EPA's waste program "would be hit hardest," this source says. "When [these offices] were created in the 1980s, the powers that be decided that there would be no scientific work within these offices, that they would rely on the IRIS program," the source says. "They've never had more than a handful of [technical] people ... They're the ones in the most trouble."

Further contributing to the waste office's troubles if IRIS is eradicated is a longstanding policy within that office that several sources pointed out, creating a tiered hierarchy of risk values that can be used by staff. The top tier consists solely of IRIS values, followed by another set of risk values EPA's research office crafts specifically for the waste office, known as the Office of Land and Emergency Management (OLEM), called provisional peer reviewed toxicity values (PPRTVs). Any other assessments are the third and lowest tier.

Richard Denison, a Lead Senior Scientist at the Environmental Defense Fund, suggests in an [April 10 blog](#) that loss of the IRIS program could also harm the toxics program. Denison points out that of the first 10 chemicals that the toxics office has selected to assess for possible risk management six have completed IRIS assessments and IRIS has started an assessment of a seventh. "EPA's ability to conduct risk evaluations under the new TSCA would be severely curtailed by the loss of both expertise and capacity that resides in the IRIS program," Denison writes.

But a former EPA official suggests that if there are no IRIS values, EPA "will default to work that has been done elsewhere," pointing specifically to risk analyses conducted in California and Europe, which the source notes will likely be more strict than regulated entities will like.

"For those people who thought the IRIS work was either too slow or too conservative, they won't have to deal with that any longer, [but] some people might wind up chuckling ... when [they] realized that the default then becomes a value that researchers in California came up with or in Europe," the former official adds. "There are a lot of people who ... they say that is a bad program, we ought to eliminate it, and they don't necessarily think about what the consequence is."

EPA Analyses

But one state toxicologist finds that unlikely, noting that EPA and OLEM in particular has a general preference for its own analyses. Still, this source suggested that eliminating IRIS would have little effect. "Every program at EPA has risk assessors and toxicologists that can do that work," says a source with the Texas Commission on Environmental Quality (TCEQ). "I think the programs can continue on."

The source acknowledged that having multiple offices in EPA perform assessments for their own purposes might lead to "some consistency issues" when different offices used different risk numbers for the same environmental contaminant. "But they'd gotten so unproductive anyway, I don't think the program offices will miss it."

The source says that he and his colleagues would like to be able to use EPA risk numbers. A lot of the values in the IRIS database, however, were 15 or more years old, the source pointed out. He added that he would like to see EPA "productive again, putting out good quality [risk] values," regardless of whether that meant "overhauling IRIS or sending the work back to the program offices. Whatever it takes to get it done. ... There's still a need for EPA to do some of this work."

TCEQ is one of a few state agencies with its own staff and resources that can produce risk numbers that form the basis for Texas' regulations. There are a few others, stakeholders note. California has the biggest program of any state, while states like Massachusetts, Michigan, Minnesota, New Jersey, New York and Washington have smaller offices devoted to risk analysis. But many smaller states, or those with limited resources, do not have the ability to produce their own numbers, leaving them dependent on other credible agencies' assessments of environmental contaminants that their agencies seek to regulate.

Former EPA sources point to the potential inconsistencies, as well as an efficiency problem created by each program office performing its own risk analyses as problems EPA addressed in the 1980s by forming the IRIS program. "You'll still need a place to harmonize the [risk] values," this source says, reminiscing of IRIS' beginning in 1986. Staff with EPA's research, water and pesticides offices met to discuss the risk values their programs had crafted. Of the total, there were tens of chemicals that all the offices had assessed, the source said, and of these all but one had different values. -- *Maria Hegstad* (mhegstad@iwpnews.com) & *Doug Obey* (dobey@iwpnews.com)

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